

REMARKS

I. Claim Rejections Based on 35 U.S.C. §102(e)

The Examiner has rejected Claims 14-16 and 18-21 under 35 U.S.C. §102(e) as being anticipated by Wong et al (U.S. 7,004,961).

With respect to Claim 14, upon which Claims 15, and 18-22 and 26-27 depend, Applicant respectfully disagrees that Claim 14 is anticipated by Wong et al. because Wong et al. fails to teach each and every element claimed by the Applicant. The method described in Claim 14 requires the insertion of a dual lumen catheter into a subdural space, followed by draining the subdural space of a subdural fluid collection with the dual lumen catheter. Wong et al. fails to disclose a method for draining a subdural space of a subdural fluid collection. With respect to the subdural space, Wong et al teaches only two methods of treatment: 1) direct cooling/heating; and 2) circulating cerebral spinal fluid (not "subdural hematomas") between the subdural space and the lateral ventricle (see Column 10, Lines 14-26). See also Declaration under 37 CFR §1.132 of Dan Lieberman, M.D., submitted herewith and incorporated herein by reference. In treating subdural hematomas, the first step must be to drain the subdural space. There is no discussion in Wong et al of draining a subdural space in order to leave the subdural space with less liquid after the

procedure than was found at the beginning of the procedure. Wong et al discloses an aspiration catheter for forcibly suctioning cerebral spinal fluid from one area of the brain (e.g., the subdural space) and delivering it to another area of the brain (e.g., the lateral ventricle) (see Column 10, Lines 46-49). Claim 14 of applicant's application teaches "draining," which is the removal of liquid, of the subdural space, while Wong et al merely circulates fluids in order to maintain the same amount of fluid (albeit of a different temperature) in the same place. In fact, Wong et al. specifically teaches away from applicant's invention by specifying the need to prevent drainage from the subdural space (see Column 8, Lines 55-57, "a one-way valve **86** or other device, disposed at the conduit proximal end **26**, prevents continual drainage of CSF **76** from the brain **60**"). The word "drain" does not appear in the Wong et al. reference, while the word "drainage" appears only three times, each time in the context of preventing drainage of fluid from the brain. Additionally, Wong et al. makes no mention of subdural hematomas or other subdural fluid collections, let alone how to drain or otherwise treat them. Because Claim 14 specifies that the subdural space must be "drained," this element must be found in the Wong et al reference. Because Wong et al. fails to teach each and every aspect claimed by the Applicant, the rejection of Claims 14-16 and 18-21 should be obviated. Applicant respectfully requests that the Board of

Patent Appeals and Interferences' decision reversing the rejection of Claims 11 and 14-25 stated in the December 11, 2008 decision on appeal be honored. It should be noted that in the Findings of Fact section of the Board of Patent Appeals and Interferences decision, the Board noted that the previous reference Wild "does not specifically teach using the disclosed surgical instrument assembly in the treatment of a subdural hematoma" (see FF12, page 7). This finding of fact is consistent with respect to the new reference Wong et al., which fails to specifically teach using it's balloon assembly for treating subdural hematomas. Just because a device is capable of entering the subdural space does not make it useful for purposes of treating a subdural hematoma. See Declaration under 37 CFR §1.132 of Dan Lieberman, M.D., submitted herewith and incorporated herein by reference.

With respect to Claim 16, Applicant respectfully disagrees that Claim 16 is anticipated by Wong et al. because Wong et al. fails to teach each and every element claimed by the Applicant. For the same reasons described above that Claim 14 is not anticipated by Wong et al. so too Claim 16 is not anticipated by Wong et al. Wong et al. teaches a device and method for rapidly cooling the neurons located in the brain area, not the non-visual treatment of subdural hematomas. This difference is critical, since the surgical device of Wong et al. utilizes a balloon which

would, by its very presence, increase the pressure in the subdural space, not reduce it, which is the proper treatment of a subdural hematoma. See Declaration under 37 CFR §1.132 of Dan Lieberman, M.D.. Applicant is a board certified neurosurgeon who has been in practice since 2000. *Id.* His practice includes the management of hundreds of patients with subdural hematomas. *Id.* Based on all of Applicant's expertise and experience in the field of neurosurgery generally and subdural hematomas specifically, the use of the Wong et al. device would prevent proper subdural evacuation of subdural fluid. *Id.* Applicant respectfully requests that the previous indication of allowability with respect to Claims 16 stated in the July 11, 2006 Office Action be restored.

## II. Claim Rejections Based on 35 U.S.C. §103

The Examiner has rejected Claims 17 and 22-25 under 35 U.S.C. §103(a) as being unpatentable over Wong et al., Claims 26 and 27 under 35 U.S.C. §103(a) as being unpatentable over Wong et al. in further view of DARDIK et al (Journal of Vascular Surgery) and Claim 11 under 35 U.S.C. §103(a) as being unpatentable over Wong et al. in view of Lanard et al.

With respect to Claim 17, Applicant respectfully disagrees that Claim 17 is obvious in light of by Wong et al.. For the same reasons described above that Claim 16 is not anticipated by Wong

et al. so too Claim 17, which depends on Claim 16 is not obvious in light of Wong et al.

With respect to Claim 22, Applicant respectfully disagrees that Claim 22 is obvious in light of by Wong et al.. For the same reasons described above that Claim 14 is not anticipated by Wong et al. so too Claim 22, which depends on Claim 14 is not obvious in light of Wong et al.

With respect to Claim 23, Applicant respectfully disagrees that Claim 23 is obvious in light of by Wong et al. For the same reasons described above that Claim 14 is not anticipated by Wong et al. so too Claim 23, which utilizes a tuohy needle to guide the insertion of the dual lumen catheter into the subdural space, is not obvious in light of Wong et al. While utilizing a tuohy needle, Claim 23, like Claim 14, is a method for treating subdural hematomas which involves the draining of the subdural space. As discussed above, there is no drainage disclosed in the Wong et al. reference.

With respect to Claim 24, Applicant respectfully disagrees that Claim 24 is obvious in light of by Wong et al. For the same reasons described above that Claim 14 is not anticipated by Wong et al. so too Claim 24, which utilizes a tuohy needle and a guide wire to guide the insertion of the dual lumen catheter into the subdural space, is not obvious in light of Wong et al. While utilizing a tuohy needle and a guide wire, Claim 24, like

Claim 14, is a method for treating subdural hematomas which involves the draining of the subdural space. As discussed above, there is no drainage disclosed in the Wong et al. reference.

With respect to Claim 25, Applicant respectfully disagrees that Claim 25 is obvious in light of by Wong et al. For the same reasons described above that Claim 14 is not anticipated by Wong et al. so too Claim 25, which utilizes a sylette in order to give the dual lumen catheter rigidity, is not obvious in light of Wong et al. While utilizing a sylette, Claim 24, like Claim 14, is a method for treating subdural hematomas which involves the draining of the subdural space. As discussed above, there is no drainage disclosed in the Wong et al. reference.

With respect to Claims 26-27, Applicant respectfully disagrees that Claims 26-27 are obvious in light of by Wong et al. For the same reasons described above that Claim 14 is not anticipated by Wong et al. so too Claims 26-27, which depend on Claim 14 are not obvious in light of Wong et al.

With respect to independent Claim 11, Applicant respectfully disagrees that Claim 11 is not obvious over Wong et al. in view of Lanard. Both Wong and Lanard fail to disclose an "irrigation channel comprising a plurality of tubes each having one end coupled in fluid communication to the distal portion of the irrigation channel, each opposite end of the plurality of tubes

coupled to the drainage channel so that the plurality of tubes support the irrigation channel inside the drainage channel while at the same time the plurality of tubes being dimensioned to deliver an irrigant from the irrigation channel to a subdural space.” (emphasis added). See Claim 11. There is no mention or suggestion in either reference of the irrigation channel having tubes that support the irrigation channel inside the drainage channel. Figures 6-8 of Lanard shows sectional views of an outlet conduit that does not support the irrigation channel. The outlet conduit of Lanard runs longitudinally along the lumen and does comprise a plurality of tubes that support the irrigation channel inside the drainage channel (see Figures 6-8). Applicant respectfully requests that the previous indication of allowability with respect to Claim 11 stated in the July 11, 2006 Office Action be restored.

#### VI. Conclusion

Applicant respectfully submits that this Amendment Letter, in view of the Remarks offered herein, is fully responsive to all aspects of the objections and rejections tendered by the examiner in the Office Action. None of the cited prior art, nor any combination thereof, discloses a method for treating subdural hematomas that includes the inserting of a dual lumen catheter into a subdural space to drain and remove a subdural

collection of fluid. For all the foregoing reasons, the Applicant respectfully asserts that all claims are patentable over the cited prior art and respectfully requests that these Claims be allowed.

The fee for a two-month extension of time is included herewith. It is not believed that this Amendment Letter requires any additional fees, but if there are any fees incurred by this communication, please deduct them from our Deposit Account NO. 23-0830.

Respectfully submitted,

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